

MARKED UP VERSION OF AMENDED CLAIMS

B1 4. (twice amended) The medication delivery system of claim 25 wherein said bolus injector is positioned in series with said infusion pump, said injector inlet is connected to said pump outlet, and said bolus injector further includes an outlet valve positioned at said injector outlet and transitionable between an open position and a closed position, wherein said outlet valve is biased to said closed position and transitioned to said open position in response to ambient pressure of a fluid medication contacting said outlet valve.

B2 6. (twice amended) The medication delivery system of claim 25 wherein said infusion pump further includes a pump flowpath providing fluid communication between said fluid storage chamber and said pump outlet, wherein said pump flowpath has a flow restriction and a drip chamber, and wherein said flow restriction is sized to convert a continuous stream of a fluid entering said flow restriction from said fluid storage chamber to a drip stream exiting said flow restriction into said drip chamber, said bolus injector is positioned in series with said infusion pump, and said injector inlet is connected to said pump outlet.

B3 25. (once amended) A medication delivery system comprising:

- a) an infusion pump including,
- a fluid storage chamber for storing fluid medication,
  - a displacement piston displaceably positionable to expand or contract said fluid storage chamber,
  - an elastic member transitionable between a more stressed position and a less stressed position to displace said displacement piston, and
  - a pump outlet for discharging a fluid from said infusion pump in response to displacement of said displacement piston; and
- b) a bolus injector positioned downstream of said fluid storage chamber in fluid communication with said fluid storage chamber, said bolus injector including,
- a flexible bladder,
  - a bolus chamber enclosed by said flexible bladder,
  - an injector inlet into said bolus chamber, and
  - an injector outlet from said bolus chamber.

## ADDITIONAL CLAIM AMENDMENTS

Cancel claim 2 without prejudice.

Add new claims 29-30 as follows:

29. A medication delivery system comprising:
- a) an infusion pump including,
    - a fluid storage chamber for storing fluid medication,
    - a displacement piston displacably positionable to expand or contract said fluid storage chamber,
    - an elastic member transitionable between a more stressed position and a less stressed position to displace said displacement piston,
    - a pump outlet for discharging a fluid from said infusion pump in response to displacement of said displacement piston, and
    - a pump flowpath providing fluid communication between said fluid storage chamber and said pump outlet, said pump flowpath including a flow restriction, a drip chamber, a sight window, and an outlet tube, said flow restriction exiting into said drip chamber and said outlet tube positioned beneath said flow restriction in said drip chamber separated from said flow restriction by a drip gap, said sight window oriented to enable visual contact with said drip chamber, wherein said flow restriction is sized to convert a continuous stream of fluid entering said flow restriction from said fluid storage chamber to a drip stream exiting said flow restriction into said drip chamber and wherein said outlet tube is configured to convert said drip stream exiting said flow restriction to a reverted continuous stream; and
  - b) a bolus injector positioned downstream of said fluid storage chamber in fluid communication with said fluid storage chamber, said bolus injector including,
    - a flexible bladder,
    - a bolus chamber enclosed by said flexible bladder,
    - an injector inlet into said bolus chamber, and
    - an injector outlet from said bolus chamber.

30. The system of claim 29 wherein said drip chamber has a volumetric center and said outlet tube has an inlet end and further wherein said inlet end of said outlet tube is positioned approximately at said volumetric center of said drip chamber.

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#### REMARKS

Claims 1-18 and 25-28 were pending in the above-captioned patent application at the time of the Office Action. The Office Action withdraws claims 11-16 from consideration as being drawn to a non-elected species and rejects claims 1-10, 17-18, and 25-28 on both prior art and non-prior art grounds. In response to the rejections, applicant amends claims 4, 6, and 25, cancels claim 2 and adds new claims 29-30. Allowance of pending claims 1, 3-10, 17-18, and 25-30 is respectfully requested in view of the above-recited amendments and the arguments set forth below.

#### Rejections Under 35 U.S.C. §112

Claim 4 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, recitation of the limitation "fluid medication" lacks antecedent basis.

Claim 6 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, recitation of the limitation "fluid" lacks antecedent basis.

Claim 25 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, recitation of the limitation "fluid" lacks antecedent basis.

Claims 4, 6, and 25 have been amended above to overcome the instant ground of rejection by correcting the language at issue.

Claims 1-10, 17-18, and 25 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In particular, the Office Action states at page 2 "The claims are

generally narrative, failing to conform to U.S. practice. They....are replete with grammatical and idiomatic errors."

Although there is no set statutory claim form, the U.S. Patent and Trademark Office requires each claim to be a single sentence. In particular, each claim must be the object of a sentence starting with either "I (or we) claim" or "The invention claimed (or the equivalent)". Each claim must also begin with a capital letter and end with a period, having no other periods in the claim except for abbreviations. *MPEP*, §608.01 (m). It is respectfully submitted that all of applicant's claims satisfy the formal requirements of the *MPEP*.

Patent claims by their nature do not follow conventional rules of grammar and style and are often laborious to read because they are necessarily drafted in a stilted style. "The drafting of patent claim language has become highly stylized and conventional. Unfortunately, prevalent drafting styles tend to emphasize clarity and precision at the expense of readability." D. Chisum, *Patents*, 1995, v. 2, at p. 8-98. "The single sentence format leads to extremely long and complex sentences - particularly in mechanical cases." *Id.* However, a claim is not unpatentable for this reason alone. Applicant has carefully reviewed the claims at issue and has not identified any grammatical or idiomatic errors except for run-on sentences which are mandated by the *MPEP*.

The definiteness requirement of §112, second paragraph, only dictates that the claims provide a clear statement to others what constitutes infringement of the patent and provide a clear measure of the invention in order to determine its patentability. D. Chisum, *Patents*, at p. 8-14. It is respectfully submitted that applicant's claims as amended satisfy this statutory requirement. Accordingly, the examiner is respectfully requested to withdraw the instant ground of rejection.

### **Rejections Under 35 U.S.C. §103**

Claims 1-10 and 25-26 have been rejected under 35 U.S.C. §103(a) as being unpatentably obvious over U.S. Patent 4,623,330 to Laby et al. in view of U.S. Patent 5,505,707 to Manzie et al. As stated at page 3 of the Office Action, Laby et al. teaches a medication

delivery system comprising an infusion pump including a fluid storage chamber, a displacement piston, an elastic member and a pump outlet. However, Laby et al. lacks teaching of a bolus injector as recited in applicant's claims 25 and 26. Laby et al. further lacks teaching of a drip chamber as recited in applicant's claims 1, 2, 6-8. Accordingly, Manzie et al. is cited for its teaching of a bolus injector and a drip chamber. The Office Action asserts that applicant's invention recited in claims 1-10 and 25-26 is an unpatentably obvious combination derived from the teaching of Laby et al. and Manzie et al.

It is well settled that a finding of obviousness requires a suggestion or motivation in the prior art whereby one of ordinary skill in the art would have combined the prior art teaching to arrive at the claimed invention. *C.R. Bard Inc. v. M3 Sys. Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998). The Office Action relies on column 1, lines 45-50, of Manzie et al. to provide the requisite motivation for combining the teaching of the two references, i.e., Laby et al. and Manzie et al., in the manner of the claimed invention. Manzie et al. states therein that prior art systems for delivering irrigating fluid to a surgical site have several disadvantages. Specifically, "it may be inconvenient or awkward for the physician to adjust the clamp to control the flow [of water] while also handling the surgical instrument. In addition, the volume and pressure of water being delivered may be difficult to control." Manzie et al. continues this discussion at col. 1, lines 51-54, "Accordingly, it is an object of the present invention [i.e., the disclosed invention of Manzie et al.] to provide a system and method that addresses or overcomes the disadvantages of the prior methods of fluid delivery to an internal body site."

From the above quoted passages of Manzie et al., it is apparent that the disclosed fluid delivery system of Manzie et al. avoids the problems of prior art fluid delivery systems. In particular, it is relatively convenient for the physician to simultaneously control the flow of water and handle the surgical instrument when using the fluid delivery system of Manzie et al. It is also relatively easy for the physician to control the volume and pressure of water delivery when using the fluid delivery system of Manzie et al. Manzie et al. overcomes the problems of prior art fluid delivery systems despite the fact that the fluid delivery system disclosed in Manzie et al. lacks an infusion pump which includes a fluid storage chamber,

a displacement piston, an elastic member and a pump outlet.

In sum, Manzie et al. teaches one of ordinary skill in the art that a fluid delivery system can operate effectively with simply a gravity driven fluid storage chamber, a drip chamber and a bolus injector. A spring driven infusion pump is neither required nor desired for effective operation of a fluid delivery system having a bolus injector under the teaching of Manzie et al. Accordingly, it cannot be said that the teaching of Manzie et al. provides the requisite motivation for combining an infusion pump with a bolus injector in a fluid delivery system as applicant's have claimed. In the absence of such motivation, the obviousness rejection is unsupported and applicant respectfully requests its withdrawal.

Claim 8 additionally traverses the instant ground of rejection because Manzie et al. lacks disclosure of a drip chamber having an outlet tube positioned therein which is configured to revert the drip stream exiting the flow restriction to a continuous stream. Manzie et al. discloses a flow chamber 413 at col. 8, lines 30-48, which functions as a drip chamber having a sight window. However, Manzie et al. is silent as to whether any structure is positioned in the flow chamber for reverting the drip stream to a continuous stream. It is respectfully submitted that newly added claims 29-30 likewise traverse the instant ground of rejection for substantially the same reason. Newly added independent claim 29 has all the limitations of amended claim 25, claim 1 and canceled claim 2. Newly added claim 30 has all the limitations of claim 29 and has additional limitations with respect to the drip chamber and outlet tube.

Claims 27-28 (and presumably claims 17-18) have been rejected under 35 U.S.C. §103(a) as being unpatentably obvious over U.S. Patent 6,247,995 to Bryan in view of U.S. Patent 5,505,707 to Manzie et al. It is respectfully submitted that claims 17-18 and 27-28 traverse the instant ground of rejection for substantially the same reasons as set forth above with respect to claims 1-10 and 25-26. Although Bryan discloses an infusion pump having two fluid storage chambers, there is no suggestion or motivation for the desirability of combining the infusion pump of Bryan with the bolus injector of Manzie et al.

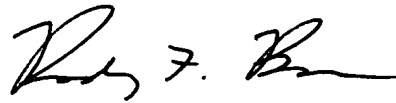
The remaining prior art references made of record and not relied upon have been

considered by applicant, but are not deemed sufficient to render the instant pending claims unpatentably obvious.

### **Conclusion**

In conclusion, applicant respectfully asserts that all pending claims 1, 3-10, 17-18, and 25-30 in the instant patent application are allowable for the reasons set forth above. Accordingly, an early notice of allowance is earnestly solicited. The Examiner is requested to call the undersigned at (858) 272-8705 for any reason that would advance the instant application to issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Rodney F. Brown". The signature is fluid and cursive, with the first name "Rodney" being more prominent than the last name "Brown".

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